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June 30, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: FDA Final Rule on New Policies, Requirements and Procedures Pertaining to the Prescription Drug Marketing Act of 1987 and Prescription Drug Amendments of 1992. 64 Fed. Reg. 67720(December 3, 1999). [Dockets Nos. 92N-0297 and 88N-1993. 0258].

Dear Sirs:

I am submitting these comments in response to the Food and Drug Administration's request for comments published December 3, 1999, regarding rules to implement the Prescription Drug Marketing Act of 1987 and modifications by the Prescription Drug Amendments of 1992.

I understand that pedigree requirements for suppliers of bulk substances used to prepare compounded medications. I prescribe a variety of compounded medications for my patients, and any disruption in the pharmacist's ability to procure substances to fill these prescriptions would threaten the health and well being of my patients.

Compounding is greatly needed in my practice. Without the ability to prescribe more exact dosages, different dosage forms and other non-commercially available medications, many of my patients would go untreated. Therefore, I urge the FDA on behalf of my ability to practice medicine in the best interest of my patients to reconsider these restrictive pedigree requirements and allow the unimpeded supply of bulk substances used in pharmaceutical compounding.

Sincerely,

Jose I. Iparraguirre, MD

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